

REMARKS

Claims 1, 3, 20, 23-25, 35-39, 43, 44, 48, and 55-58 have been amended. Claim 42 has been cancelled. Claims 6, 9, 11-13, 21, 26-34, 40, 41, 47, and 49-51 were cancelled in a previous Response(s). Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 43-46, 48, and 52-58 are presented for the Examiner's review and consideration. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendments to the Claims

Claims 1, 24, 25, 35, 43, 44, and 48 have been amended to clarify that the elongated insulation sleeve is positionable to limit/control the application of energy from the energy source to the retainer, sutures, gapped portions of the device, and/or surrounding tissues. The positionability of the sleeve enables precise control of the energy utilized for bonding of the sutures and/or retainers while simultaneously protecting the surrounding tissues from potentially-damaging contact with the energy. No new matter has been added. These amendments are supported in the specification as originally filed. *See paragraphs [0064]-[0067]; [0537]-[0542]; and Figures 52-55 of the published application; U.S. Patent Application Publication 2004/0230223 A1; hereinafter "published application."* The closed-sleeve position is illustrated in Figure 54 and the open-sleeve position in Figure 55.

Claim 35 has been amended to include a safety switch operably-connected to the insulation sleeve. No new matter has been added. This amendment is supported in the specification as originally filed. *See paragraph [0542] of the published application.*

The remaining amendments were made only for consistency of language and/or to provide proper antecedent basis for terms recited in the claims.

Restriction/Election

In the Office Action mailed on April 20, 2007 the Examiner determined that the application discloses three species of ultrasonic applicators (Species IA-Figure 24; Species IIA-Figure 25; and Species IIIA-Figure 48) and required an election. In the Response filed on May

21, 2007 Applicants elected Species IIIA-Figure 48. Figure 48 shows a sectional view of the horn/anvil ultrasonic energy application apparatus illustrated in Figure 25. Thus, Species IIA and Species IIIA are essentially the same species. *See* paragraphs [0036]; [0060]; [0371]; [0372]; and [0520] of the published application. Furthermore, claims, *i.e.* claims 4 and 7, drawn to a device including an acoustic horn have already been examined.

Thus, Applicants respectfully request that the requirement for election be withdrawn, at least with regard to the election of species of ultrasonic applicator.

Examiner's Response to Previous Arguments

Prior to addressing the rejections, Applicants address two assertions in the current Office Action. First, the Examiner asserts that a previous amendment “further narrowed the scope of the independent claims by amending the term ‘slidably’ to ‘controllably’. Applicants respectfully disagree. The amendment speaks for itself and does not require any characterization. Second, the Examiner asserts that Applicants “acknowledged that the previous rejection was proper by making this amendment.” Applicants respectfully disagree. The amendments were made in an effort to advance prosecution and no concession as to the appropriateness of the rejection was made or should be implied.

Rejections under 35 U.S.C. §103(a)

Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston et al. U.S. Patent 3,513,848; hereinafter “Winston.” in view of Yoon U.S. Patent No. 5,908,429; hereinafter “Yoon.” Claims 52-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston in view of Yoon and further in view of Bates et al. U.S. Patent No. 6,348,056 B1; hereinafter “Bates.”

For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches and not to argue each reference separately.

Winston

Winston, which has been discussed in detail in previous Responses, (incorporated herein by reference), is limited to the application of ultrasonic energy to sutures. In particular, Winston discloses an apparatus and a method for forming sutures using ultrasonic vibrational energy. *See abstract.* The apparatus is illustrated in Figures 3, 3A, and 11. This apparatus includes vibrator means **45a** in the form of a hand held instrument, including an ultrasonic transducer or motor **65a** for effecting the high frequency vibrations of the tool member **55a**. The tool member **55a** has an enlarged portion **57a** terminating in a work surface **56a** and a base **66a** secured to insert portion **67a**. The apparatus further includes support means **46a** that acts as an anvil or clamp, so that overlapping layers of suture thread **39a** and **40a** may be compressed between working surface **56a** and a support surface **49a** provided on the vibratory and support means. *See column 10, lines 3-19.* The apparatus and method of Winston help to eliminate the loosening of a suture after its formation, and thus maintain tension in the sutures. *See abstract and column 3, lines 51-53.*

Yoon

Yoon discloses methods of anatomical tissue ligation. Specifically, Yoon discloses the steps of introducing a distal end of a single anatomical tissue ligation instrument assembly at an internal operative site in a patient's body, grasping anatomical tissue at the internal operative site with a grasping member of the anatomical tissue ligation instrument assembly disposed at the distal end, positioning a contractile ligature loop formed of a length of filamentous ligature material of the anatomical tissue ligation instrument assembly around the anatomical tissue while the anatomical tissue remains grasped by the grasping member external of the distal end, contracting the ligature loop around the anatomical tissue to form a ligature and severing the length of ligature material proximally of the ligature to separate the ligature from the remainder of the length of ligature material. *See Abstract.*

In an embodiment, Yoon discloses that a grasping instrument **16** can be designed to supply energy to anatomical tissue to treat the tissue. For example, grasping instrument **16** can

be provided with an electrical connector **61** coupled with inner member **38**, in which case the inner member **38** and grasping members **50A** and **50B** are made of electrically conductive material. Electrical connector **61** is adapted to be connected with a source of electric current for transmission of electricity via the inner member **38** to treat anatomical tissue contacted by grasping members **50A** and **50B**, such as for electrical cautery or coagulation. Where the inner member **38** is designed to transmit electricity, it is preferable that the outer member **36** be made of electrically insulative material. As shown in FIG. 5, the outer member has an additional longitudinal slot **37** through which connector **61** extends, the slot **37** permitting longitudinal movement of the outer member **36** and/or the inner member **38** relative to the other since the connector **61** is slidable along the slot **37**. In addition, it is desirable that the grasping instrument **16** be longitudinally movable relative to barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel for safety and protection, and it is preferable that the barrel be made of electrically insulative material. It should be appreciated that the grasping instrument can be designed to transmit various forms of energy including electricity, laser, ultrasound and cryoenergy. *See column 8, lines 34-59.*

The anatomical tissue ligation instrument assembly **10** can be used to treat anatomical tissue at the internal operative site with energy. For example, FIG. 15 illustrates the grasping members **50A** and **50B** grasping the stump of tissue structure **T** therebetween with electricity being supplied to the stump via the tips **54A** and **54B** of the grasping members **50A** and **50B** for electric cautery to control bleeding. *See column 15, lines 30-36.* Thus, Yoon teaches application of energy to the tissue and mentions nothing to minimize application of the energy to the suture/ligature material or to minimize damaging amounts of energy being applied to the tissue.

Bates

Bates discloses medical instruments (and methods for using the instruments) for capture and/or release of materials within the body, for example gall stones and urinary tract stones. *See abstract; column 1, lines 5-10; and column 3, line 26-column 4, line 13.* The instrument is designed such that it can capture and release material while the instrument is still positioned within the body. *See column 2, lines 2-6.*

The embodiment cited in the Office Action is shown in Figures 11a and 11b. A sheath **12** adjacent the handle includes a slot **14**. The sheath **12** is operably attached to a pin **18** movable in a slot **14**. When the pin **18** moves in the slot **14** from the distal position shown in FIG. 11a to the proximal position shown in FIG. 11b, the sheath **12** also moves in the proximal direction as shown in FIG. 11b. As the sheath **12** moves proximally, the proximal portion **22** of the retrieval assembly expands as it is uncovered by the distal sheath end **15**. *See* column 10, line 61-column 11, line 2.

Instant Invention

The instant invention, as currently claimed in independent claims 1, 24, 25, 35, 43, 44, and 48, provides a surgical device for securing tissue, the device including an elongated insulation sleeve that is controllably positionable over the second member, tubular member, and/or force-transmitting member. The positionability of the elongated insulation sleeve enables precise control of the application of energy from the energy source. The sleeve is positionable to limit application of energy to a retainer and/or the gapped portion of the device. Likewise, when the retainer is used with a suture, the suture is shielded from the energy. Additionally, when the device is in use the surrounding tissue is protected from potentially-damaging contact with the energy. In one embodiment (claim 35), a safety switch prevents energy from being applied until the elongated insulation sleeve is in a certain position. For example, *see* paragraphs [0014]; [0064]-[0067]; [0537]-[0542]; [0093]-[0098]; [0542]; and Figures 3 and 52-55 of the published application.

Argument

Applicants respectfully submit that the combination of the teachings of Winston and Yoon or of Winston, Yoon, and Bates does not obviate the invention as currently claimed. Independent claims 1, 24, 25, 35, 43, 44, and 48, recite, *inter alia*, a surgical device for securing tissue, the device including an elongated insulation sleeve that is controllably positionable over the second/tubular member. The positionability of the sleeve enables precise control of the

energy utilized for bonding of the sutures and/or retainers while simultaneously protecting the sutures, retainers, and/or surrounding tissues from potentially-damaging contact with the energy.

The Examiner asserts that Winston discloses the device as currently claimed with the exception of a specific compressive force and an insulating sleeve and that Yoon supplements these teachings by disclosing an instrument designed to transmit various forms of energy controllably positioned into an insulated sleeve. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to produce the claimed device by providing Winston with the sleeve of Yoon.

Applicants respectfully disagree. The combination of references neither provides nor suggests a device having the capabilities (application of energy and positionability) of the device as currently claimed.

Yoon purportedly discloses an instrument designed to transmit various forms of energy controllably positioned into an insulation sleeve. Applicants agree that in the instrument of Yoon, the instrument slides within a stationary sleeve. However, this is not relevant to the claimed invention as the insulation sleeve of the claimed device is not stationary, but rather slides over the second/tubular member. This distinction is easily surmised. For example, the Examiner considers element **12** of Yoon to be equivalent to the elongated insulation sleeve of the claimed device. Applicants disagree. Yoon discloses element **12** as a “barrel” made of electrically-insulative material. The fact that two tubular elements are insulated is not sufficient in and of itself to render the elements equivalent. As described by Yoon, a tissue-grasping instrument **16** is disposed within barrel **12** and can be designed to supply energy to tissue. The tissue-grasping instrument **16** is longitudinally movable with regard to the barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel, *i.e.* the tissue-grasping instrument **16** slides within barrel **12**, barrel **12** does not slide over the tissue-grasping instrument **16**. Thus, the barrel **12** is stationary with respect to other elements of the device. Further, the grasping instrument **16** is retractable for the safety and protection of the instrument itself, since the instrument can not grasp and/or supply energy to tissue while in the retracted position. *See* column 5, lines 41-48; column 8, lines 34-59; and Figures 1, 2, and 5. Therefore, in contrast to the Examiner’s assertion, barrel **12** can not be considered equivalent to the elongated

insulation sleeve of the claimed device, since it (barrel **12**) is clearly not controllably positionable or even capable of independent movement. Furthermore, Yoon discloses sleeves **28A**, **28B**, and **28C** disposed within and fixedly secured to barrel **12**. *See* column 5, line 65-column 6, line 18. Accordingly, the movement/positionability of the sleeve of the currently-claimed device is impossible to achieve using the either the barrel or the sleeves of Yoon's device with Winston's device.

Furthermore, the utilization of energy by Winston's device is not akin to the utilization of energy by Yoon's device, *i.e.* energy is not applied to the same elements to achieve the same results.

Winston discloses an apparatus for forming/securing sutures by applying ultrasonic vibratory energy to the overlapped free end segments (on opposite sides of tissue to be sutured) of suture material which has been conventionally applied to a patient. *See* column 3, line 69-column 4, line 12. Thus, in operation of Winston's device, energy is applied directly to the suture(s). Winston does not describe any element of the device useful to limit/control application of energy to the suture and/or to protect the surrounding tissue from potentially-damaging contact with the energy.

Yoon discloses a single-instrument apparatus for performing anatomical tissue ligation, including the treatment of tissue with energy, wherein energy is applied directly to the tissue. *See* column 2, lines 1-10; column 4, lines 47-48; column 8, lines 34-35; column 18; lines 20-30; and Figure 24. Thus, in operation of Yoon's device, energy is applied to tissue and not to the sutures/ligature material (as in Winston). Yoon does not describe any element of the device useful to apply and/or limit application of energy to the ligature material/suture or to limit/control the amount of energy applied to the tissue.

Thus, it is clear from the above discussions that the combination of the teachings of Winston and Yoon lacks all of the elements of the device as currently claimed; *i.e.* the combination does not describe an elongated insulation sleeve that is controllably positionable to provide precise control of the energy utilized for bonding of the sutures and/or retainers while simultaneously protecting the surrounding tissues from potentially-damaging contact with the energy. Therefore, merely surrounding the device of Winston with the sleeve of Yoon would not

result in the device of the claimed invention, but rather with a non-functional device in which the energy source to the overlapped ends of a suture is blocked by an immobile sleeve.

Even if one incorrectly determined that the combination of Winston and Yoon teaches all of the elements of the claimed invention, the fact that one reference discloses an element(s) of an invention and a second reference discloses another element(s) does not, in and of itself, render the claimed invention an obvious combination of the two references.

“The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made.” In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

Even in the rare instance that one would combine the disclosures of Winston and Yoon, in light of the above, why would one of ordinary skill in the art be motivated to provide the device of Winston with a sleeve as described by Yoon? Do the references suggest that the device of Winston would be improved by using a sleeve such as that described by Yoon? Applicants respectfully submit that they (the cited patents) do not make any such suggestion, and in fact suggest the opposite, *i.e.* that a protective sleeve would not be necessary for Winston’s device. Thus, motivation to combine is non-existent.

The Examiner asserts *“Given the teachings of Yoon, it would have been obvious to have provided Winston with such a sleeve, in order to protect the user and the patient from possible burns, while providing a sleeve through which the device could be inserted in order to suture internally.”*

Applicants respectfully disagree. Winston views his invention as an improvement over the use of a hot iron to fuse knots of a plastic suture and states:

“As compared to the hot iron technique for fusing plastic knots as hereinabove discussed, ultrasonic welding is accomplished at a relatively cool temperature. Accordingly, the support means 46b or even the vibratory means 45b may be placed in engagement with the biological organism 20b without causing any damage thereto. This is not possible with a hot iron in which any slip of the iron, which could easily occur, would burn the tissue it engages.” Column 12,

lines 41-48. *See also column 2, lines 54-57, wherein disadvantages of the hot iron technique are discussed.*

Since Winston teaches that his device is useable at “cool temperatures” and that it (the device) can engage biological tissue without causing damage, why would one be motivated to cover the device with a sleeve positionable to limit/control application of energy to sutures and/or tissues? In contrast to the Examiner’s reasoning, by teaching that energy applied with his device is harmless to tissue, Winston actually suggests that a protective sleeve, whether movable or not, is unnecessary to prevent burns.

Furthermore, Yoon does not teach or suggest that a sleeve or any other element is necessary to protect the ligature materials or tissues from exposure to the energy. Thus, there is nothing in Yoon that would motivate one of ordinary skill in the art to use the sleeve with the device of Winston or with any other known device for protective means against application of energy to sutures and/or tissues, especially since Winston teaches his device protects patients from burns.

Neither the cited patents (Winston and Yoon) nor any other prior art teach or suggest a surgical device for securing tissue; the device including an elongated insulation sleeve that is controllably positionable over the second/tubular member to provide precise control of the energy utilized for bonding of the sutures and/or retainers while simultaneously protecting the sutures, retainers, and/or surrounding tissues from potentially-damaging contact with the energy. Additionally, considering that devices for securing tissue are absent from the disclosure of Bates, the addition of Bates as a secondary reference does nothing to remedy the deficiencies of the combination of Winston and Yoon. Thus, even if one of ordinary skill in the art were to combine the teachings of Winston and Yoon and/or of Winston, Yoon, and Bates, the surgical device, as currently claimed, would not be the result.

Accordingly, Applicants submit that independent claims 1, 24, 25, 35, 43, 44, and 48 are patentable over Winston in view of Yoon and/or Winston in view of Yoon and further in view of Bates. As claims 2-5, 7, 8, 10, 14-20, 22, 23, and 52 depend from claim 1; claim 53 depends from claim 24; claim 54 depends from claim 25; claims 36-39, 45, 46, and 55 depend from claim 35; claim 56 depends from claim 43; claim 57 depends from claim 44; and claim 58 depends

from claim 48, these dependent claims necessarily include all the elements of their base claims. Thus, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Yoon and/or Winston in view of Yoon and further in view of Bates at least for the same reasons.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 43-46, 48, and 52-58 under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a two month extension of time pursuant to Section 1.17(a)(2) in the amount of \$245 and the fee for a request for continued examination pursuant to Section 1.17(e) in the amount of \$405 are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

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